

K012410 INFINITY HBA KIT, MODELS 537-A, 537-BOct 26, 2001
88 days to decisionK012410 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k012410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jul 30, 2001
Decision date	Oct 26, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT II
510(k) history	164 submissions · 164 cleared · 1984-2002

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